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Sent: Wednesday, July 28, 1999 6:46 PM
To: FDADockets@oc.fda.gov
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Subject: Docket Number 98N-0044

Please accept the following comments on your proposed new definition on "Structure/Function" statements:

A. Definition of Disease - The current definition is sufficient with a few caveats. There is no mention of disease causing organisms such as bacteria and viruses, autoimmune syndromes, injury. The mention of what can cause disease would be an important addition to the definition as it would help define drugs. Some drugs are specifically designed to fight pathogens or other disease mechanisms. Because dietary supplements are designed to treat or prevent disease of deficiency, diseases of deficiency should be exempted for the definition or they must all be considered drugs. That would take us back in time nearly 100 years. It was not the intention of congress to get rid of dietary supplements with the creation of DSHEA not is it the wish of the American people. It is a legitimate use of dietary supplements to treat disease of deficiency

B Common conditions associated with natural states Nutrient deficiencies are a part of the natural state of man. Iron is the most abundant element on the planet yet nearly 1 billion people world wide are iron defficient. This has been the case for thousands of years so it is clearly a natural state of the species. Vitamin deficiency has always been the natural state of man - witness the prevalence of scurvey before the understanding that citruss could prevent it. Witness the incidence of rickets before we understood that sunlioght could prevent it (and later vitamin D). - Nutrient deficinecies are a natural state of man.

C Implied Disease Claims - Obviously, nutritional deficiencies can lead to diseases (e.g. scurvy, anemia, pellagra, rickets, etc...) There is no more perfect way to treat these syndromes than with dietary supplements. To adopt the new definition would prevent a seller of vitamin C from saying that this will help prevent scurvy even though this truth has been known for hundreds of years - ask any limey!!! Why does the FDA want to go back to the dark ages and prevent people from stating the truth on dietary supplement labels? This is a direct contradiction to the DSHEA Act and is contrary to the will of the American people and laws written by congress. In our opinion, this is an obvious attempt by a humiliated agency that lost power after overreaching its authority, to take back power to which it has no right and to "Show who's boss" by clandestinely and unde handedly stealing back power from the American people.

The agency doesn't need new definitions, it needs to enforce the laws that exist today. Preventing the honest and open flow of legitimate information on labels is draconian, and wrong headed. This is not in the best interest of the American people, Enforcing the laws that are already on the books is.

Sincereley,
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Microbiologist

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